IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

KIMBERLY C. CUTONE and, ANTHONY CUTONE Plaintiffs, v. ELI LILLY AND COMPANY, Defendant.	)	Civil Action No. 04-CV-12725 (JLT)

AFFIDAVIT OF AARON M. LEVINE, ESQ.
REGARDING AUTHENTICATION OF DOCUMENTS

I, Aaron M. Levine, declare under penalty of perjury that the following is true and correct:

1. Attached as Exhibit 1 is a true copy of Defendant Eli Lilly and Company's Responses to Plaintiffs' First Set of Interrogatories and First Request for Production of Documents and/Or Tangible Things in Wilson v. Eli Lilly and Co., et al., 04-CV-01193 (TPJ/AK) (D.D.C. Jul. 15, 2004)(incorrectly labeled 04-CV-0682), dated March 18, 2005.

2. Attached as Exhibit 2 is a true copy of a selected page from FDC Reports: Drugs And Cosmetics, The Pink Slip (F-D-C Reports, Inc., Aug. 10, 1959).

3. Attached as Exhibit 3 is a true copy of selected pages from FDC Reports: Drugs And Cosmetics, The Pink Slip (F-D-C Reports, Inc., Sept. 6, 1947).

4. Attached as Exhibit 4 is a true copy of selected pages from FDC Reports: Drugs And Cosmetics, The Pink Slip (F-D-C Reports, Inc., May 29, 1961).

5. Attached as Exhibit 5 is a true copy of selected pages from FDC Reports: Drugs And Cosmetics, The Pink Slip (F-D-C Reports, Inc., Aug. 10, 1959).

6. Attached as Exhibit 6 is a true copy of selected pages from FDC Reports: Drugs And Cosmetics, The Pink Slip (F-D-C Reports, Inc., Jan. 3, 1948 and May 13, 1957).

7. Attached as Exhibit 7 is a true copy of selected pages from FDC Reports: Drugs And Cosmetics, The Pink Slip (F-D-C Reports, Inc., Mar. 22, 1947, Mar. 29, 1947 and June 21, 1947).

8. Attached as Exhibit 8 is a true copy of selected pages from Eli Lilly and Company, De Re Medica, Editio Tertia (1951) at 212-214.

9. Attached as Exhibit 9 is a true copy of selected pages from Eli Lilly and Company, The Modern Apothecary, 31, 88 (H.S. Noel ed., 1941).

10. Attached as Exhibit 10 is a true copy of the Amended Statement of Philip J. Cafferty, dated October 22, 2003 and signed November 17, 2003.

I declare under the penalty of perjury that the foregoing is true and correct.

/s/ Aaron M. Levine
Aaron M. Levine

Dated: July 7, 2006

CERTIFICATE OF SERVICE

I, Erica Tennyson, hereby certify that this Affidavit of Aaron M. Levine, Esq. Regarding Authentication of Documents, filed in support of Plaintiff's Opposition to Defendant Eli Lilly's Motion to Strike the Statement of Philip Cafferty, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on July 11, 2006.

/s/ Erica Tennyson
Erica Tennyson

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

KIMBERLY A. WILSON, Plaintiff, vs. ELI LILLY AND COMPANY, et al., Defendants.	Civil Action No. 04-CV-0682 (TPJ/AK)

DEFENDANT ELI LILLY AND COMPANY'S RESPONSES TO PLAINTIFF'S FIRST SET OF INTERROGATORIES AND FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND/OR TANGIBLE THINGS

COMES NOW defendant Eli Lilly and Company (hereinafter "Lilly"), by and through its attorneys, Foley Hoag, LLP, pursuant to Rules 33 and 34 of the Federal Rules of Civil Procedure, and provides the following responses to Plaintiff's First Set of Interrogatories and First Request for Production of Documents and/or Tangible Things to Defendant Eli Lilly and Company.

PRELIMINARY STATEMENT

As a preface to each and every response to plaintiff's interrogatories and requests, Lilly qualifies its response by stating that Lilly has not completed its investigation of the facts relating to this case, has not completed its discovery in this action and has not completed its preparation for trial. Lilly reserves the right to amend or supplement these responses as discovery in the case progresses, as new facts are developed and as new information is obtained. Therefore, the following responses are given without prejudice to Lilly's right to produce any additional evidence at trial or in connection with any pretrial proceeding.

Some of the events relevant to this action occurred over sixty (60) years ago. Due to the lapse of time, many of the individuals having personal knowledge of these events are deceased or otherwise unavailable and many of Lilly's documents are no longer available. As a consequence, Lilly's responses to these interrogatories and requests are necessarily limited by, and subject to, these qualifications.

The term diethylstilbestrol, as used in these responses, refers only to diethylstilbestrol. It does not refer to any chemically similar synthetic estrogen-like substance or to any congener of diethylstilbestrol.

GENERAL OBJECTIONS

OBJECTION A: Lilly objects to these interrogatories insofar as they seek information for time periods beyond March 31, 1957, the date of birth for plaintiff Kimberly A. Wilson, on the grounds that such information is not relevant to any issue in this lawsuit and would not lead to the discovery of admissible evidence. It is apparent that no action by Lilly, its employees or any other person subsequent to that date could have any effect upon plaintiff Kimberly A. Wilson's alleged exposure to diethylstilbestrol.

OBJECTION B: Lilly objects to these interrogatories to the extent they seek information unrelated to the use of diethylstilbestrol for the prevention of certain accidents of pregnancy. The prescription drug, diethylstilbestrol, was approved by the Food and Drug Administration (FDA) for a variety of human uses other than use as an aid in the prevention of certain accidents of pregnancy. These indications did not involve the use of diethylstilbestrol in pregnant women, the only use that plaintiff alleges in her complaint and the only use relevant to this action. Accordingly, information concerning other uses for diethylstilbestrol is irrelevant and has no bearing upon the issues in this case nor is discovery into those uses reasonably calculated to lead to the discovery of evidence admissible at trial.

OBJECTION C: Lilly objects to these interrogatories to the extent they seek information concerning the manufacture, distribution or sale of diethylstilbestrol in sizes and forms other than 5 and 25mg oral dosage forms, on the grounds that information concerning dosage sizes other than those indicated for use in prevention of accidents of pregnancy is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence.

OBJECTION D: Lilly objects to these interrogatories to the extent they seek information relating to injuries or adverse effects other than those alleged by plaintiff on the grounds that such information is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence.

OBJECTION E: Lilly objects to these interrogatories to the extent they seek information protected by the attorney-client and/or the attorney work product privilege.

OBJECTION F: Lilly objects to these interrogatories to the extent that they are irrelevant and not reasonably calculated to lead to the discovery of admissible evidence.

OBJECTION G: Lilly objects to these interrogatories and definitions on the grounds that they are vague and overbroad to the extent they may exceed the scope of discovery allowed pursuant to the Federal Rules of Civil Procedure.

INTERROGATORIES

1. Witness

Identify each and every individual(s) known to you, your attorneys or investigators, who may have any information concerning the identity of the brand of diethylstilbestrol ("DES") to which the Plaintiff was exposed in utero.

RESPONSE: Lilly incorporates herein its objections E and G. Lilly further objects to this interrogatory as an improper attempt by plaintiffs to require Lilly to prepare plaintiffs' case. Lilly further states that plaintiff has the burden of proving the facts necessary to

establish the elements of her alleged cause of action, including the cause of her alleged injuries. Without waiving and subject to its objections, Lilly states that it has not completed its investigation and discovery in this matter, and cannot fully respond to this interrogatory at this time. Because such information is not within the direct knowledge of Lilly, Lilly can only respond to the extent that the information is obtained through discovery, which is still ongoing. At the present time, the witnesses identified by plaintiff may have information concerning the manufacturer(s) of any medications plaintiff Kimberly Wilson's mother allegedly ingested during her pregnancy with plaintiff.

2. Lilly Wholesalers

Identify the Lilly distributors or wholesalers serving the alleged city of exposure during the relevant time period, and describe any agreements made between you and them regarding giving preference to Lilly products, or attach the agreement(s) to your answer.

RESPONSE: Lilly incorporates herein its Objections A, B and C. Without waiving and subject to its objections, Lilly states that through the relevant time period it sold its pharmaceutical products FOB Indianapolis, Indiana to independent drug wholesalers located throughout the United States, who, in turn, sold to retail druggists. Lilly states that for the time period relevant to plaintiff's mother's pregnancy with plaintiff, the pharmaceutical wholesalers located in the Bedford, Massachusetts area who were authorized to carry Lilly's pharmaceutical products, as well as the pharmaceutical products of other manufacturers, were:

Gilman Brothers, Inc.
100 Shawmut Avenue
Boston 4, Massachusetts

James W. Daley, Inc.
672-680 Washington Street
Lynn, Massachusetts

McKesson & Robbins, Incorporated
385 Summer Street
Boston 10, Massachusetts

Lilly no longer has records showing sales or shipments of its pharmaceutical products to particular pharmaceutical wholesalers during the period in question. Lilly did not sell pharmaceutical products directly to physicians, hospitals, or pharmacies. Further answering, Lilly states that a representative copy of the contract which would have been in effect with Lilly's wholesalers in the Bedford, Massachusetts area for the time period relevant to plaintiff's mother's pregnancy with plaintiff, is attached at Tab A.

3. Adverse Reports to the FDA

List any specific reports or studies you provided to the FDA, in any application or communication with that agency, concerning possible risks to the daughters from in utero DES exposure. Do not refer to your NDA but cite with specificity the particular study which provided such information.

RESPONSE: Lilly incorporates herein its Objections A, B and D. Lilly further objects to this interrogatory to the extent it assumes as true facts at issue in this lawsuit. Lilly further objects to plaintiff's definitions and instructions to the extent they exceed the scope of the Federal Rules of Civil Procedure and seek to prevent Lilly from providing a full and accurate response. Lilly further objects to this interrogatory to the extent it seeks information concerning the thought processes of all Lilly employees: it is impossible for Lilly to answer an interrogatory involving the thought processes of its employees over many years. Lilly cannot state when any specific person at Lilly became aware of a specific article.

Lilly further objects to this interrogatory to the extent it may assume that studies using pregnant animals are necessarily meaningful with respect to pregnant women, an assumption which Lilly disputes. Whether an animal is an appropriate model for testing the

effects for a drug on a biological system depends on a variety of factors, including the physiologic similarity of the animal to the human.

Without waiving and subject to its objections, Lilly states that during the period in which Lilly indicated diethylstilbestrol for use in pregnancy, neither Lilly nor, to the best of Lilly's knowledge, anyone else had received information that a serious or long term adverse effect on the human fetus was considered to be causally related to the use of diethylstilbestrol during pregnancy by the mother.

Further answering, Lilly states that it kept abreast of the published medical literature on diethylstilbestrol and related subjects shortly after they were published in the medical and scientific literature. Lilly was aware of articles appearing in the published literature reporting certain experimental effects produced in the offspring of animals exposed to diethylstilbestrol *in utero*. Lilly submitted citations to some of these reports to the FDA through its NDAs for diethylstilbestrol. A list of those citations has previously been made available to plaintiff's counsel.

Further answering, Lilly states that Dr. Don Carlos Hines, Lilly's Medical Monitor for diethylstilbestrol from 1940 through 1952, has testified that during that time he attempted to read all medical articles published in English and in major foreign language journals about diethylstilbestrol and related subjects. The only articles or studies Lilly can identify with certainty upon which it relied for the development and preliminary testing of diethylstilbestrol are (1) those submitted to and/or cited to the FDA in its NDAs, and (2) the articles listed in Lilly's product literature for its diethylstilbestrol. Such articles included, but were not limited to, publications concerning animal studies with diethylstilbestrol and other estrogenic substances. Those articles, in turn, would have referenced other possibly relevant publications.

Dr. Hines further testified that the medical community was aware that animal studies involved the use of dosage regimens which far exceeded clinical dosage sizes. and the prevailing medical opinion did not consider such studies to be clinically applicable. In a 1941 report by Ronald R. Greene published in the American Journal of Obstetrics and Gynecology, Volume 42, pages 858 to 861, Dr. Greene makes the following statement regarding the effects of diethylstilbestrol on experimental animals:

> The fact that tremendous overdoses of estrogens are capable of producing truly toxic effects in experimental animals is. however. not of clinical importance. There are few substances of therapeutic value which are not toxic when given in equally tremendous overdoses.

4. White Cross Score

Do you contend that in the year of exposure as set forth in the Complaint, any manufacturer other than you, bottled or distributed DES in the dosage sizes indicated for use in prevention of accidents of pregnancy, as a round, white cross-scored non-imprinted tablet? If your answer is yes, identify the product or the manufacturer and any documents (by date, description or custodian) upon which you rely in making this statement. For your information. it appears that the Squibb 100mg was imprinted with their name and that the Amfre-Grant was hexagonal.

RESPONSE: Lilly incorporates herein its Objection E. Lilly further objects to this interrogatory on the grounds that it is irrelevant because there is no evidence that the product allegedly ingested by plaintiff's mother was a "round, white cross-scored non-imprinted tablet." Lilly further objects to this interrogatory to the extent it assumes that all of Lilly's diethylstilbestrol in dosage sizes indicated for use in the prevention of certain accidents of pregnancy was round. white, non-imprinted and cross-scored.

Respectfully submitted.

ELI LILLY AND COMPANY

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FILE

LILLY MARKET SHARE

THE NEWS THIS WEEK

T&G TRADE & GOVT. MEMOS: (Pages 15 - 17)

* Los Angeles Drug's whsle. volume up 4.6%, from $17.3 to $18.1 mil.
* D. Kaltman adds 2 to board, sets up exec cmte. for expansion.
* Colgate-Palmolive paid $1.67 mil. in stock for Sterno Corp. (canned heat).
* Bergen Drug's, NJ whslr., FT family petition plan seeks 250,000 signers.
* B-M & Sterling healthy 2nd quarter nets follow drug-cosmetic pattern.
* Carrtone Labs to set up 50-50 in Puerto Rico with local MD's.
* FDA's delisting order will carry some colors for at least nine months.
* Vet drug escape hatch may come through revised "safety recognition" setup.
* Squibb's vet hormone growth promoter to get zero tolerance petition.
* Deafness from dihydrostreptomycin probed by FDA for regulatory action.

** FEDERAL FT DRIVE gains new momentum, may achieve this year's objective -- House passage -- if supporters can bring in necessary "back home" pressure to lift House Rules Cmte. blockade. State pharmaceutical secretaries building up steam for FT from home offices and by Washington visits. Ohio trying to marshall same force that pushed state law over veto.

States' righters propose new obstacle to effective federal FT during Rules Cmte. hearings, started Aug. 3 and continuing Aug. 10. They may propose far-reaching amendments from House floor which would nullify effective national FT system, and invite sure-fire veto from President. Sen. Humphrey may try to get FT bill action in Senate this year to put controversial issue behind him before start of presidential election year.

(Page 3)

** INDEPENDENT DRUG STORE is in sound financial condition, even though a substantial number of pharmacies showed poorer '58 records, the 27th Lilly Digest indicates. Independent druggists' average ratio of assets to liabilities is 3.5-to-1, good cover for current obligations, but report shows 15% of pharmacies operating at a loss in 1958 -- highest in

(PLEASE TURN PAGE)

THE NEWS THIS WEEK
(continued)

recent years -- and another 15% reporting less than 2% net on sales. Lilly Digest figures and American College of Apothecary operating results on stores with comparable total average volumes indicate pharmacist-owners of general-type stores (with good Rx depts.) have better takes (net-plus-withdrawals). Rx refills continue post Durham-Humphrey upward spiral. (Page 12)

** NATL. HEALTH FEDERATION, an organization which gave Rep. Delaney its annual award in '58, asks Congress to spend some govt. medical research funds in "drugless fields of healing." In testimony before a House Interstate subcmte. hearing on a bill to create an international medical research institute, Harold Edwards, Federation VP, stressed benefits that might result from greater interest in nutrition. "Cancer over the ages has yielded to a dietary of simple foods," he tells subcmte.

Citing chiropractors as largest group in drugless field, Edwards asks for few "sorely needed" dollars for research in this area. Delaney's award acceptance speech before Federation last Oct. tells how he got cancer clause into food additive law and gives clue to his McCarthy-like hold over FDA. Natl. Federation, with 10,000 dues-paying members in 300 chapters, has headquarters in San Francisco, but maintains Washington office to watch over health matters during Congress. (Page 6)

** NUTRITIONAL QUACKERY is costing 10 million Americans $500 mil. each year according to AMA estimates, Wallace Janssen, FDA Public Information Div. director, warns in U.S. Public Health Service publication. He says food faddism has aspects of organized movement. (Page 10)

** COLOR ADDITIVE LEGISLATION will have to be bought by industry on a "pig-in-a-poke" basis, but the alternative is going without coal tar colors, according to a highly-placed FDA official, commenting on the probability that none of the 17 colors facing FDA delisting are likely candidates for immediate provisional listing under the color additive bill. Looks like lever to force drug support for new law. (Page 11)

** DRUG RESEARCH REPORTS ("The Blue Sheet"), an affiliate of "F-D-C," will have stories in Aug. 12 issue on: Eisenhower weighing establishment of new medical research advisory council along lines urged a year ago by Pharmaceutical Mfrs. Assn.; Merck's Connor, testifying before House subcmte. on international research bill, says matching basis for foreign grants OK for industrialized Europe & Japan but won't accomplish purpose in underdeveloped areas -- also discloses Russian claim to invention of Sabin oral polio vaccine which was furnished by his co. Bill won't pass House this session.

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general US business conditions. It looks like inventory adjustment is completed; more normal buying is replacing hand-to-mouth operation. One co. reports that 4 of its popular priced Christmas sets were sold out before Labor Day; another co. -- tops in dentifrices and mass commodity items -- reports sales are up. Old line houses are trying not to oversell market on holiday goods; they want to avoid last yr.'s experience on returns.

There's no lack of cosmetic advertising and promotion plans. Though the rate has declined from the high of 18 months ago, there are still a number of new products being introduced or en route. The number of new cos. has dropped, and smaller ones have fallen by the wayside. Advertising straws in the wind: Lady Esther's million dollar lipstick campaign; Kathryn's (the Harry Daumits') half-million dollar campaign for Nu-Youth, $1 hormone cream; Toni's purchase of time for 6th net show bringing its total ad budget for next yr. up to $6 million; Lambert's search for a fall network show; Kreml's addition of a Billy Rose radio show; and many others, including reorganized Associated which is spending $110,000 this fall on Chen Yu -- deglamourized, hard selling copy.

Other straws in the wind: Lambert and others have mass distribution products on test -- shave creams, deodorants, etc. Burma-Vita has a tooth powder. Corday is bringigg out its first post-war perfume, Fame at $18 per oz.; Coty is returning Chypre to the line. While Dana cut prices 20%, most other big perfume names have not followed suit. Mens' lines have settled down for the long pull -- in the popular priced field there's a noticeable trend to $1 sets. Premiums and special deals are being used -- Squibb's toothpaste, Jergen's Lotion and Dryad; Woodbury's Cream and Fiesta powder; Williams' introductory free tube of shave cream; Associated Merchandising's new packages for While Lilac private brand.

* * * * * DRUGGISTS GET THEIR BEST RETURNS ON PROPRIETARIES, according to a report by American Druggist's John McPherrin before APhA convention. Formally titled "Economics of Rx Practice", but re-titled "Are you making any money?", report was based on an experimental cost of operations and time study made in a single "guinea pig" drug store and financed by a well known wholesaler. This store made 45% gross on Rx's but had an operating loss of 6% when expense was allocated -- "loss" amounted to $100 per month. McPherrin said pharmacist must charge at least $3.00 per hr. for his time -- not $1.50 as most do now.

Soda fountain in pilot store wasn't making any money, either. It was doing 23% of dollar volume but at a net loss. Rx dept. in this store accounted for 7% of total volume; proprietaries 19%. But instead of losing money, proprietaries more than carried their load -- they returned 37% of gross profit and 23% of the net. Periodicals, with their fast turnover, made 12% of the net. Similar time studies on a broader basis are indicated to shed more light on drug store operations.

'46 Lilly Digest shows drug store profit-sales ratio going down with rising dollar volume. Based on over 1,000 stores, '46 profits were 8.6% of sales compared to 9.5% in '45 and 9.8% in '44. Decline in profit ratio is attributed to

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CALIF. Rx FEE ANTITRUST TRIAL DELAYED FOR A WEEK; DEFENSE FILES NEW DISMISSAL MOTION RESTATING PROFESSIONAL ARGUMENT

The May 22 opening of the Northern Calif. Rx fee schedule criminal antitrust trial was delayed for a week when Federal Judge Louis E. Goodman, who was assigned to hear the case, rescheduled the starting date to Thur., May 25, and later again postponed the start of the trial until Mon., May 29, (today). The delay resulted from Judge Goodman's hospitalization for diagnostic tests.

¶ Defense attorneys, meanwhile, filed a new motion for dismissal of the criminal antitrust indictment against the Northern Calif. Pharmaceutical Assn. (NCPA) And Donald K. Hedgpeth, pharmacist who prepared the Rx fee schedule widely used by NCPA members.

¶ The new motion again raises the basic issue of whether a pharmacist, in dispensing an Rx drug, is merely selling a commodity that has moved in interstate commerce or is rendering a professional service that removes his action from the areas of trade and commerce covered by the antitrust statutes.

The defendants, their counsel, and prosecuting attorneys for the Justice Dept.'s Antitrust Div. appeared on Mon., May 22, as scheduled, before Federal Judge William T. Sweigert who was serving as the assignment judge for the San Francisco Federal Court. He assigned the pharmacy antitrust case to Judge Goodman.

Professional Fees Exempt From Antitrust, APhA Contends

The defense got a break when the case was sent to Goodman. This eliminated fears that the trial might be heard by Federal Judge Lloyd H. Burke, who had previously indicated strong feelings when he rejected a defense motion on March 20 for postponement of the trial until next fall.

In refusing to delay the trial until next fall, Burke said the public interest was keenly involved. From the bench, he raised the question of whether patients who had paid for Rxs on the basis of the fee schedule could initiate private, triple-damage antitrust suits if the govt. won the criminal case. The San Francisco daily newspapers headlined his comments ("F-D-C" March 27).

The 13-man slate of Atlas directors elected at the Mar. 27 meeting did not include any Stuart officers. The merger statement said Atlas "has agreed to use its best efforts, subsequent to the merger, to cause Arthur Hanisch ... to be elected a VP and director of Atlas" -- or, if he chooses not to serve on the board, to elect a nominee of his choosing, so long as the Stuart principal stockholders own 300,000 Atlas common shares.

Hanisch will continue to direct the Stuart operation. After full conversion, Hanisch, Pelletier, and Pringle combined will own 580,140 new Atlas shares -- 13.8% of the total to be outstanding.

Chemicals accounted for almost 50% of Atlas's $70.9 mil. sales in 1960 and about 58% of the $3.0 mil. earnings. Research expenditures were 6% of sales -- about $4.3 mil.

The Atlas proxy statement, stating "Reasons for the Merger," said that "a major expansion" in the company's research and development has taken place over the past decade." As a result of expansion in food additives, it said, Atlas "has developed skills for evaluating physiological effects of numerous compounds. Utilization of these skills in the drug field appears desirable." Reflecting the merger, the corporate name will be changed to Atlas Chemical Industries, Inc.

Over the past several years, profit ratios for Stuart have been much better than for Atlas. A pro forma comparison, assuming combined operations, indicates a striking potential improvement in Atlas's gross and net ratios from the merger -- assuming Stuart's ratios will continue to be as favorable as they were up to 1960.

Chairman-President of Atlas is Ralph K. Gottshall, who owns 2,366 shares of Atlas's 763,100 total outstanding (pre-split). Gottshall drew $72,327 remuneration in 1960. Other salaries were: $65,154 for Exec VP Edward J. Goett, $50,040 for VP Edward J. Massaglia, and $46,733 for new VP Max E. Colson. Atlas's total assets at Dec. 31, 1960 were reported as $55.5 mil., compared with Stuart's $4.9 mil.

Atlas sales of explosives reached a record high in 1956, but have been encountering vigorous competition from fertilizer-grade ammonium nitrates.

ATLAS & STUART RATIOS-TO-SALES

	Atlas		Stuart	
	1960	1959	1960	1959
Cost of Goods Sold	65.3%	64.9%	32.9%	32.9%
Sell., Adm., Gen. Exp.(a)	21.2	19.8	48.8	42.3
Net Before Taxes	8.2	10.1	18.4	24.8
Net After Taxes	4.2	5.5	9.5	12.5

(a) Atlas Cost of Goods Sold and Expenses do not include depreciation & amortization -- 4.8% of sales each year.

LILLY REVISES WHSLR. DISCOUNTS -- FROM FLAT TO VARYING MARGINS; CHOICE WAS BETWEEN CHANGING DISCOUNTS OR WHSLR.-ONLY MARKETING

Lilly's switch from a straight-line, uniform whslr. discount to a system of "varying discounts" -- announced to its whslrs. last week -- represents an effort by the pharmaceutical firm to remain competitive and still maintain its traditional "whslr.-only" distribution policy.

Effective July 1, Lilly will replace its long-time uniform whslr. discount of 15 & 7% with a set of three discounts -- one for each of three categories of products into which its entire line is being divided.

¶ The largest category -- volumewise -- consisting chiefly of trademarked pharmaceutical specialties, will have a discount of 16-2/3%.

¶ The vitamin category, including trademarked specialties as well as "competitives," will have a 20% discount.

¶ An Rx parenteral category will have discounts of 10% and 16-2/3%, and whslrs. will be encouraged to pass on the 10% to retail pharmacists as an incentive for increasing the volume of Lilly products marketed in this highly competitive area where MDs are the major customers.

> Faced with the mounting costs and competitive pressures that have combined to cause the current pharmaceutical marketing revolution, Lilly virtually had to make a choice between abandoning its traditional whslr.-only policy or bringing its whslr. discount structure more into line with the realities of today's drug market.

Beesley Cites "Today's Competitive & Rapidly Changing Markets"

No dyed-in-the-wool Lilly man could ever concede that the company had given a moment's thought to abandoning its whslr.-only policy. Recent Lilly operating statements and the current facts of pharmaceutical marketing life, however, made it evident that the company had to give serious consideration to changing either its distribution policy or its discount structure.

> ¶ The new discount structure, Lilly President Eugene Beesley explained in a brief public statement, "will facilitate the distribution and selling of Lilly merchandise in today's competitive and rapidly changing markets."
>
> ¶ "As a result of continuous study," Beesley declared, "it is our conviction that distribution of Lilly merchandise through the whslr. continues to best serve the public's health needs and the professional and business interests of pharmacy and medicine."

The new discount structure, the Lilly president predicted, "should place both the Lilly whslr. and the Lilly Company in a better position to compete successfully for the expanding markets for pharmaceutical products."

> All the figures, marketing logic and explanations in the world, however, won't convince whslrs. that they will be better off with lower discounts. Within the past year, they've had a series of jolts from other pharmaceutical houses, and drug whslrs. are faced with their own critical figures and operating problems.

Lilly historically provided the business bulwark for its selected group of franchised whsle. distributors which totaled 344 in the U.S. at the end of 1960. Its uncompromising whslr.-only distribution policy and its wide, unvarying discount have served to underwrite the economics of the so-called "full line, service" whsle. drug distribution system.

In effect, the Lilly policy and the Lilly discount helped to carry the costs of servicing retail pharmacists with other lines and products that were unprofitable for the whslr. The Lilly system almost guaranteed the franchised whslr. a profit for staying in business.

> This made the whslr.'s business life a lot easier. He didn't have to face the hard choice of eliminating unprofitable lines and products.

New Margins Make Lilly Products Stand On Their Own Feet, Too

The wide margin on Lilly products and other pharmaceuticals even helped the whslr. carry less essential, lower-yield lines and items that the retail pharmacist has historically handled and has greatly expanded in recent years as chains and other competition have widened their merchandise lines.

The revision in the Lilly discount, on top of the earlier changes in marketing policy by other pharmaceutical houses, means that the whsle. druggist, more than ever, must re-evaluate his entire business operation to make certain that all his lines and products carry their own weight in costs and profits.

> The whslr.'s loyalty, in fact, will be put to an unprecedented test by the Lilly change. Whslrs. reacted violently to the earlier changes by other pharmaceutical mfrs., and it remains to be seen whether they will recognize that Lilly had to revise its discount in order to maintain its whslr.-only policy.

The Lilly revision also serves to put the products in its own line on a self-carrying basis. This is indicated by the way in which the three new Lilly product categories are being established. The pharmaceutical specialty category, for example, contains products that depend largely on the company's promotion program and detail staff for their sales volumes.

These are products which the MD must prescribe before a sale can be made, and there is little the drug whslr. can do to increase the volume on them. His function is to maintain adequate distribution. Apparently Lilly felt that this justified the lowest discount. Whslrs. have been handling the distribution function for similar products of other mfrs. at the same discount.

> Lilly obviously felt that a higher discount was justified for its vitamin and "competitive" category because this one includes products whose sales volume can be influenced, in a measure, by the activity of whsle. druggists and their salesmen.

In the days before the era of pharmaceutical specialties, the Lilly policy and discount worked well for both the company and its whslrs. because a large share of the volume was in "competitive" products whose volume could be increased by zealous whslr. support. With the advent of specialties, the relative share of volume for "competitives" dropped sharply.

Lilly specialties now must compete with strong and entrenched pharmaceuticals marketed by other companies -- big and little. Under the new competitive conditions, Lilly couldn't live forever off the "whslrs.' love." And in the long run, if Lilly lost out in the competitive race, the flat, higher margins wouldn't have meant too much to the whslrs.

> The Lilly policy and discount, in effect, meant that Lilly consistently received less from the sale of products than its competitors received from the sale of theirs. Lilly President Beesley had to remind Sen. Kefauver (D-Tenn) of this when he appeared before the Senate drug hearings last fall.

Lilly Still Adheres Strictly To Principle Of Fair Trade

Kefauver was comparing the whsle. prices of penicillin products from various pharmaceutical mfrs. when Beesley called his attention to: "The price that Lilly receives is less a discount of 15 & 7% which would bring that down substantially." The same situation was brought out during the polio vaccine antitrust trial.

The 10 & 16-2/3% discount on Lilly's third new category of products -- Rx parenterals -- obviously was designed to introduce greater flexibility into its pricing of these highly competitive items. This change indicates that Lilly will push for a greater share of the mass-markets that are rapidly increasing, both in size and in competitive activity.

The new Lilly whslr. agreement also will provide greater flexibility to compete for hospital business, bulk orders and special offers. Its hospital list is being expanded from tax-supported to include all tax-exempt ones. But nothing in the new Lilly program changes its strict adherence to the principle of fair trade.

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FEDERAL FT DRIVE FOR HOUSE PASSAGE HAS NEW LIFE, BUT RULES CMTE. HEARING SHOWS NEW THREAT: STATES RIGHTS' AMENDMENTS

The federal fair trade (FT) drive on Capitol Hill, which came to life again two weeks ago ("F-D-C" Aug. 3), has continued to gain momentum and there is a good chance that this year's objective -- passage by the House -- can be achieved, if FT supporters can produce the necessary amount of mail and telegrams from "back home" to convince Congress that "small business" really wants the Harris bill.

¶ The House Rules Cmte. held a hearing Mon. Aug. 3 on clearing the Harris bill for a vote on the House floor, and the all-powerful cmte. is continuing its consideration of the measure on Mon. Aug. 10. The Rules Cmte. will send the bill to the House floor if it is convinced there is enough pressure behind it from the folks back home.

¶ A new threat to the enactment of an effective federal law was disclosed when states' righters indicated at last week's Rules Cmte. hearing that they might propose amendments on the House floor which could nullify the basic purpose of the Harris bill -- establishing a national FT system.

State Pharmaceutical Sectys. Building Steam at Home and in Washington

After its Aug. 3 hearing, the Rules Cmte., which had been blockading the FT bill, laid the measure aside for the rest of the week while it considered the controversial labor-management anti-racketeering bill. With Congress hoping to go home by Labor Day, the Harris bill must get out of the Rules Cmte. in a few days to avoid being crushed in the last-minute rush to adjournment.

The new life in the FT drive results from increased activity on the part of all supporters. NARD's Dargavel has been in Washington. A group of Washington trade assn. execs, representing non-drug retailers, met with House Interstate Cmte. Chairman Harris (D-Ark.) last week to show him that there is widespread support among all types of small businessmen behind his bill.

State pharmaceutical secretaries also have been building up the steam for FT -- from their own offices back home and by visiting Washington. FT's slim majority on the 12-man House Rules Cmte. may well depend on NY Secty. Gesoalde's contacts with Rep. Delaney (D-NY). Mass. Secty. Silverman is working on a wave of telegrams in hopes of showing Rep. O'Neill (D-Mass.), a member of the Rules Cmte., how his vo rs feel. O'Neill also represents an important vote on the Rules Cmte.

AVERAGE INDEPENDENT DRUG STORE IS IN SOUND FINANCIAL CONDITION, BUT OPERATING STATEMENTS INDICATE PROBLEMS, LILLY DIGEST SHOWS

The average independent drug store is in sound financial condition -- despite a record of 1958 operations that was poorer than 1957 for a substantial number of pharmacies -- it is indicated in the 27th Lilly Digest report to be distributed in a few weeks. The Lilly figures show the independent druggist's average ratio of assets to liabilities is almost 3.5 to 1, thus indicating an ability to take c[illegible] of current obligations. About 58% of his assets are in merchandise invent[illegible].

Lilly's 1958 study included the operations of 2,429 stores -- nearly 5% of the total number of independent pharmacies. (See table below for average balance sheet figures, weighted to compensate for the larger volumes enjoyed by the stores reporting to the Lilly Digest as compared with drug stores in general.)

The independent druggist's financial strength is important to manufacturers, wholesalers, and the drug field as a whole because he continues to constitute the major channel of distribution. In 1958 independents accounted for nearly 80% of the $6.6 bil. . . total retail drug volume reported by Commerce Dept.

The Lilly Digest's average volume figures for 1958 differed from Commerce Dept. data. Average store volume was reported by Lilly as $126,191 in 1958, down slightly from the Digest's average of $126,466 for 1957. Commerce reported total retail drug volume up 4.3% in 1958 over 1957, with independent gaining 3.7%

Lilly explained its 1958 study included a large[r] proportion of low-volume pharmacies than in 1957. A separate tabulation of 747 pharmacies which reported to Lilly in both 1957 and 1958 showed an average volume increase of 5.8% for these stores.

LILLY DIGEST AVERAGE BALANCE SHEET FOR INDEPENDENT DRUGGISTS

(Weighted to compensate for larger volume of Lilly Digest stores)

	12/31/58		12/31/57	
Assets:				
Cash	$ 3,530	11.9%	$ 3,650	13.0%
Inventory	17,150	58.0%	15,980	56.8%
Fixtures, equipment	6,320	21.4%	6,140	21.8%
Accts. receivable	2,250	7.6%	2,080	7.4%
Other assets	320	1.1%	290	1.0%
Total assets	$29,570	100.0%	$28,150	100.0%
Liabilities and Net Worth:				
Accts. payable	$ 4,310	14.6%	$ 4,080	14.5%
Notes payable	3,550	12.0%	3,440	12.2%
Other liabilities	620	2.1%	590	2.1%
Total liabilities	$ 8,480	28.7%	$ 8,110	28.8%
Net worth	21,090	71.3%	20,040	71.2%
Total liabilities and net worth	$29,570	100.0%	$28,150	100.0%

Based on average net-plus-salary, the owners' take from 300 Lilly Digest pharmacies, whose average volume was closest to that reported by ACA, was higher -- both percentagewise and in actual dollars.

The following table compares the ACA average figures with the Lilly averages for pharmacies having (1) the closest comparable percentage of Rx to total sales and (2) closest total volumes:

	Lilly (60 to 75% Rx) (93 pharmacies)	ACA (158 pharmacies)	Lilly ($150-$200,000 sales) (300 pharmacies)
Total store volume	$97,082	$174,150	$173,669
Rx volume	66.1%	58.1%	
Gross margin	42.5%	42.1%	34.5%
Total expenses	35.4%	37.6%	29.2%
Net profit before taxes	7.1%	4.5%	5.5%
Net plus owner's salary	20.7%	11.8%	13.4%
Average inventory	$15,327	$29,118	$26,439
Inventory turnover	3.6 times	3.4 times	4.3 times
Inventory % of sales	15.8%	16.7%	15.2%
Average no. of Rx's	21,095	36,289	
Average Rx price	$3.04	$3.10	

Rx Refills Continue to Spiral Upward --Despite D-H Law

Rx business averaged 32.4% of total volume in 2,158 Lilly Digest pharmacies. In addition, Lilly noted that sales of non-Rx merchandise through the Rx dept. -- including over-the-counter pharmaceuticals plus Rx accessories -- "has been estimated" at 5 to 1[illegible] of total sales, thus pushing total Rx dept. sales over 40% of total store vol[illegible].

Lilly Digest data also highlighted the fact that Rx refills "continue upward spiral." Refills made up 47% of the total Rx business in the Lilly stores in 1958, compared with less than 46% in 1957. Since the 1951 passage of the Durham-Humphrey (D-H) amendment to the federal food and drug law, which tightened control of refills, the refill ratio has risen to this point from 42.5% -- despite predictions that the new law would sharply constrict refill business.

> Noting that the refill ratio fell in 1952 and 1953, Lilly commented: "This may have been a short-term after-effect of the passage of the D-H Act.... In 1956, Rx refills surpassed the pre-D-H record, and since then they have continued steadily upward."

"It seems probable," the Lilly Digest said further, "that after the 1952-1953 readjustment period, refill business was stimulated by the federal regulations. Practicing pharmacists immediately launched educational campaigns regarding the provisions of the law, and these produced a substantial increase in the number of Rx's which bore specific refill instructions."

The Lilly Digest made special note, however, that some of the stores it surveyed in 1958 were "barely able to match their record in 1957, and others entered a decline." The tabulation showed 15% of the reporting pharmacies operating at a loss in 1958 -- highest in recent years -- with another 15% reporting less than 2% net on sales.

These data suggest that the "inventory recession" felt by many drug-cosmetic mfrs. and whslrs. in 1958 may have been due in part to actual sales declines in independent drug stores. Independents, who are inclined to key their inventory policies to the diminishing frequency of cash register rings, apparently cut back on stock replacements. A reversal of this trend is evident in booming whsle. drug volume thus far in 1959.

Lilly also noted a "slight squeeze" on drug store net profits in 1958, with average net-before-taxes -- not including proprietor's withdrawals -- dropping from 5.5% of sales to 5.2%. Expenses rose 0.4% of sales, but three-fourths of the increase was in proprietor's withdrawals, and total income (net plus proprietor's withdrawals before taxes) remained at 13.2% of sales -- unchanged from '57.

Cost of Goods Rate & Turnover Rate Lower Than 10 Yrs. Ago; Gross Margin Up

Lilly showed the independent's average gross margin in 1958 was 34.7%, virtually unchanged from 1957. For 1958, 1957, and 1949 -- a decade ago -- Lilly reported operating ratios as follows:

	1958	1957	1949
Cost of goods sold	65.3%	65.4%	67.6%
Gross margin	34.7	34.6	32.4
Proprietor's salary	8.0	7.7	7.6
Employees' wages	11.2	11.2	10.5
Rent	2.2	2.2	2.6
Other expenses	8.1	8.0	5.8
Total expenses	29.6	29.1	26.5
Net before taxes	5.2	5.5	5.9
Annual turnover rate	3.8%	3.9%	4.0%

The 1958 Lilly Digest continued to emphasize the importance of Rx business to total store income and profit. It includes scores of breakdowns analyzing operations in relation to (1) proportion of Rx volume to total sales and (2) number of Rx's filled daily -- both further broken down by volume brackets. For the 2,158 stores that reported specific Rx dept. data, Lilly said Rx gross margin averaged 47% of the selling price.

A comparison of Lilly Digest data with figures reported earlier by the American College of Apothecaries (ACA) seem to indicate that the pharmacist-owner -- based on his net-plus-salary -- does better with a general-type drug store (if it has a good Rx volume) than with an exclusive Rx shop. The Lilly Digest pharmacies include general-type stores and the ACA survey was based on figures from 154 exclusive Rx shops.

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Can the manufacturers write label directions that are "adequate" within the meaning of the F-D-C law for the safe and efficacious use of this product? If not, the Rx legend would be the only alternative, according to top F&DA officials. At the same time, these officials wish to have it understood that they are not seeking to apply the Rx legend; i.e., to restrict, veterinary medicinals. Rather, it has been the policy of F&DA to leave it to the manufacturer to adopt labeling with adequate and safe directions for effective use. They say it is the intention of the Administration to permit the widest possible distribution of veterinary products consistent with the interest of the livestock and poultry raiser. It is only in this respect that F&DA's labeling policy on animal remedies is different from the corresponding policy with reference to human medication, where the welfare and safety of the individual patient is the deciding factor.

New Legend Was Devised for Vet. Sulfonamides

It has become well-recognized that the present Rx label regs. issued in Oct. 1945, set up an extensive drug classification system with respect to labeling requirements (see "14-Point Yardstick for Drug Labeling, F-D-C REPORTS, June 16, 1945). In the main, the classification of drugs under these regs. has been largely confined to products for human use. But veterinary medicinals also fall into different classes under the regs. F&DA veterinarians warned several months ago that labels of certain highly potent drugs would have to be revised, and if adequate directions could not be prepared the products would have to be restricted. Lack of an adequate diagnosis was seen as the weakest point in lay medication of livestock (F-D-C REPORTS, June 28, 1947).

At the time it was presumed in some quarters that the only solution to the problem would be to use the Rx legend: "Caution: To be dispensed only by or on the prescription of a (physician) (dentist) (veterinarian)." Subsequently, however, the labels of certain sulfonamide preparations were revised to include a different legend: "For safe and efficacious use of this product as directed an adequate diagnosis must be obtained from a state diagnostic laboratory or a practicing veterinarian." In this instance manufacturers are considered to have obviated the need for the Rx legend by devising a direction which F&DA considered "adequate."

Served Notice on Diethylstilbestrol Last July

F&DA served notice it was not satisfied with proposed labeling for over-the-counter sale of diethylstilbestrol products for livestock (F-D-C REPORTS, July 26, 1947). At that time officials said that in the light of information then available they did not see how farmers could safety and intelligently use the proposed product for any practical purpose. They said that no labeling had been received which could be considered free of objectionable features. Apparently, F&DA officials have receded very little if any from this position. Discussing labels they have seen recently F&DA men say their principal shortcoming is a tendency to claim too wide a field of use -- making the product a cure-all. However, one manufacturer has produced what F&DA-ers regard as a satisfactory

label, which gives directions for only one use -- to produce a so-called false heat period -- and cautions against breeding the cow until the natural heat period (and ovulation) occurs.

In the past, diethylstilbestrol has been advocated for expulsion of retained afterbirth, but according to F&DA veterinarians it has recently been shown to be useless for this purpose, and may even cause sterility. Other claims on which F&DA casts a doubtful eye include increasing milk production, correction of sterility of bulls and cows, clearing infections of the genito-urinary tract, correction of "slow pigging" and "slow lambing." Respecting the latter, F&DA veterinarians note that in human beings the drug is used to prevent abortion, rather than to induce it.

* * *F-D-C * * *

TARIFF CUTS DEFERRED ON SOME DRUG-COSMETIC ITEMS - Presidential proclamations this week put the Geneva Trade and Tariff Agreements into effect, but made exceptions in the case of numerous items imported from countries which have not yet ratified the multilateral understandings. Thus the United States will not accord lower duty rates to these commodities until the producer nations take action giving like treatment to U.S. products.

Products of interest to the drug-cosmetic industries on which tariff concessions have been deferred (duty remains unchanged) include the following:

Antimony (tartar emetic), caffeine citrate, caffeine compounds, medicinal preparations containing alcohol, ipecac and mate, castor oil, cottonseed oil, peanut oil, soybean oil, bottles and jars (unfilled), perfumery ware (machine or hand blown, filled or unfilled), salicin, lactose, oil bearing seeds, ginger root, spices, still wines and bristles. The list, itemized by tariff classifications, was published in the Federal Register of December 30. * * * F-D-C * * *

* * * ISOLATION OF COLD VIRUS was described by US Public Health Service Drs. Norman Topping and Leon T. Atlas in report in "Science" and a Dec. 24 press conference. Virus was used to produce colds (thick sort, not the runny nose type) in DC reformatory prisoner volunteers. At press conference, the researchers said they considered the work significant, but warned it points only to possibility not probability of producing a vaccine. * * * F-D-C * * *

* * * RECENT AMA COUNCIL ACCEPTANCES: Influenza Virus Vaccine, Types A & B -- Pitman-Moore (incidentally, co. employees are getting shots free), Sharp & Dohme, Squibb; Gold Sodium Thiomalate, a gold salt for treatment of active rheumatoid arthritis -- Merck Solution Myochrysine; Choline Dihydrogen Citrate for treatment of hepatic diseases -- Flint, Eaton Syrup Choline Dihydrogen Citrate; Mannitol to measure flomerular filtration -- Sharp & Dohme Sterile Solution of Mannitol; Dinesterol oral estrogenic compound -- White Labs.

* * *F-D-C* * *

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CANADIANS FIND DIETHYLSTILBESTROL ACCUMULATES IN POULTRY; F&DA WILL NOT ALLOW USE IN FEEDS

Use of diethylstilbestrol in poultry feeds for the purpose of tenderizing male birds will not be permitted in the U.S., Food & Drug Administration officials indicated this week following receipt of news that the Canadian Ministry of Health and Welfare has banned all sale of synthetic estrogens for this purpose. Apparently the Canadian authorities have even ruled out the use of the 15 mg. pellets which F&DA has okayed for caponizing young roosters, via subcutaneous insertion in the neck. In Washington it was indicated that F&DA would not go as far as the Canadian Food & Drug Division.

Action of the Canadian authorities is based on the report, by Division researchers Bird, Pugsley and Klotz, that when estrogens are fed to roosters for tenderizing a sufficient quantity accumulates in the fatty tissues to be harmful to the human consumer. This is believed to be the first scientific report that estrogenic substances are accumulated in the tissues in a dangerous amount.

No New Drug Applications have been made effective here for use of diethylstilbestrol in feeds, but several are reported to be in effect covering the 15 mg. pellets. It is believed that this method limits the amount that each bird can receive, while providing for slow absorption. Cooking is considered a further safeguard in the event a bird with an unabsorbed pellet should reach the consumer. In any event, F&DA-ers say, a 15 mg. pellet is not a big enough dose to be likely to have any effect on a human being. They say on the other hand that larger quantities would have to be used in the feed in order to have any tenderizing effect, and that this method of administration apparently accounts for the accumulation reported by the Canadian scientists.

The Canadian developments have made F&DA take an even more cautious attitude on the pending question whether to okay the use of thiouracil for quick-fattening of livestock (F-D-C, 11/8/47).

* * *F-D-C* * *

DIRECTION TO CHANGE WATER IS F&DA MINIMUM INRE LABELING OF POULTRY WATER DISINFECTANTS

In considering its position regarding quaternary ammonium compounds for use in poultry drinking water (F-D-C, 11/8/47), the Food and Drug Administration has reached the conclusion that so-called drinking water disinfectants should at least carry label directions advising that the water should be changed frequently to avoid pollution with organic matter.

F&DA veterinarians and bacteriologists say such pollution will nullify any potential value which the products may have in preventing the transmission of disease from one bird to another. The F&DA-ers are frankly skeptical of the effectiveness of the widely sold drinking water disinfectants, but admit they are not in a position to say they are no good. They just haven't got enough scientific

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NDA on the ground that it was "incomplete." If the Hepasyn matter had been brought to a formal hearing, it is believed that FDA also would have challenged the safety of the drug by bringing efficacy and control methods into the proceeding.

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IN BRIEF: "Ends dandruff" claim for over-the-counter medicated shampoos is under serious regulatory scrutiny by both FTC and FDA -- FTC staffers are understood to have recommended formal complaint v. one mfr. . . . . Strike at P-D's Detroit plant ("F-D-C" May 6) was ended via signing of two-year contract with machinists union. . . . NYC attorney Sigmund Eisenstein petitioned Supreme Court for review of contempt conviction of Dolcin Corp. and its President van der Linde for violating FTC ad order ("F-D-C" Apr. 15). . . . Colgate is reported firing about 100 -- including several long-service marketing execs -- in latest shake-up designed to cure ailing profits situation. . . . Warner-Lambert Chairman Elmer Bobst received NYC Cancer Cmte. 's Clement Cleveland award for outstanding work in the campaign to control cancer. . . .

Walgreen's volume for 6 months ended March 31 was $116.2 mil. compared with $108.7 in '56 period; net after taxes $2.3 mil. against $2.1. . . . FDA won permanent consent injunction v. Nulsar ulcer remedy -- reportedly similar to Exul. . . . Lilly sued Drug Fair chain for violation of Md. FT law. . . . Drug Fair chain stock offering ("F-D-C" Apr. 22) went on market last week, sold out immediately. . . . German Bayer (Farbenfabriken Bayer -- survivor of I. G. Farben combine) expects its total sales to reach $476 mil. in 1957 . . . .

Max Factor upped three sales execs to VP-ships: Sidney Factor, Alfred Firestein, and Menache Politi . . . Similar "hazardous articles" bills (S 1900 and HR 7388) introduced by Sen. Bush (R-Conn.) and Rep. Curtis (R-Mo.) -- "F-D-C" April 22, In Brief -- would exempt drugs and cosmetics conforming with current FDA labeling requirements. . . . In anti-merger case, 2nd Circuit Court ruled that FTC subpena covers not only records of respondent co. (A.G. Spalding, sports goods) but also confidential reports of trade association members (Athletic Goods Mfrs. Assn.) to assn. 's accountants (Ernst & Ernst) to be used in compilations. . . .

Lever's Pepsodent is fair trading its new Dove soap -- believed to be first mass-market toilet soap to be put on FT. . . . Denver Chemical upped Thomas J. Morrissey to sales manager. . . . Dr. Francis A. Mina -- who headed aerosol development for Zonite (now Chemway) -- joined Lodes Aerosol Consultants as technical director. . . .

After multiple-seizing thermometers of various mfrs., FDA started a criminal prosecution v. Cardinal Thermometer Co. on charges thermometers are inaccurate and otherwise substandard. . . . Dr. James O. Hoppe, Sterling-Winthrop researcher, was awarded the '57 Chilean Iodine Award -- $1,000 and a citation -- at the NYC APhA convention for his studies on iodinated organic compounds. . . . FDA approved streptomycin inhalation solution for chickens; product will be marketed by Eastern Labs, Vineland, NJ, which already has a streptomycin aerosol for poultry

F-D-C REPORTS

Drugs and Cosmetics

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P-D's '46 SALES $66.2 MILLION LEADS PHARMACEUTICALS

Parke-Davis, Abbott and Sharp & Dohme annual reports released this week (stories on p. 10-12, WHITE SECTION), provide data for tabulation of sales figures on top firms whose business is primarily in pharmaceutical field -- and whose corporate structures require publication of data. P-D topped the list with '46 sales of $66.2 million -- up $11.6 from '45. Squibb, which reports on a fiscal yr. basis, was second with $59.8 million sales for yr. ending June 30, 1946 --up $6.3 from yr. previous -- Squibb profit statement for 6 months ending Dec. 31, 1946, indicates sales were holding up, or better, justifying second ranking despite divergence of annual report dates. However, Squibb sales include a major cosmetic operation on which separate figures are not available. Abbott with '46 sales of $54.2 million -- up $16.3 -- ranks third. Sharp & Dohme with $26.6 million -- up $1. -- is fourth. Mead Johnson with $22.9 million -- up $4. --is fifth.

Eli Lilly doesn't report financial data. Only published figures available are sales of $27.7 million for '43, reported by FTC's Chief Statistician Roger Barnes in Nov. '45 testimony before a House Judiciary subcmte. Merck, whose operations might be considered primarily in the medicinal chemical field, reported '46 sales of $61.5 million -- up $5.9. Pfizer, primarily a bulk medicinal chemical producer, had $43.6 million sales in '46 -- up $16.1. Johnson & Johnson, which has diversified beyond surgical dressings in recent yrs., reported '46 sales at $112.6 million -- up $16.6 million. Bauer & Black's figures are blanketed in with its parent Kendall Co.'s sales, which cover widespread textile operations-- Kendall reported '46 sales at $87.4 million -- up 24%. Norwich's '46 sales were $10.2 million -- down $1.6 from '45, but net income and net per share for '46 was up. Sales of Wyeth, Winthrop, Stearns, Merrell, J. T. Baker and some other pharmaceutical operations are grouped in with figures reported by parent companies which operate in widely diversified fields.

MAY 12-18 ARE DATES FOR FTC COSMETIC CONFERENCE

No official FTC announcement on specific dates yet, but it's indicated Commission will accept industry proposed dates -- the 2 days prior to annual Toilet Goods Assn. convention in NY. Current private discussions center on efforts to draft a rule, acceptable to FTC, which would permit cosmetic manufacturers to buy promotional services -- i.e., trained sales personnel, co-op

(F-D-C REPORTS, March 22), may fall off; (5) Expanded activity and increased sales volume is straining cash positions; Sterling's Jim Hill highlighted this in his annual report (p. 1, WHITE SECTION)-- others are in the same boat.

Here's the cosmetic situation as summed up by a top industry exec: "I have just returned from a several weeks business trip through the Middle West, and, frankly, in my 24 yrs. in the cosmetic business and traveling the country, never have I found business conditions as stagnant and hesitant as they are today." Dept. and specialty stores, primarily so-called 'prestige' outlets, hit the cosmetic industry.. hard with pre-Christmas cancellations and post-Christmas returns (some cosmetic cos. excepted). Then came what appeared to be a leveling off period (F-D-C REPORTS, Feb. 15) -- but some action is required soon to hold the plateau. Not so hard hit, apparently, are sales of cosmetics via drug and syndicate stores, particularly so-called mass distribution popular-priced lines."

STERLING'S '46 SALES $121.4 MILLION -- 72% MEDICINES

With possible exception of Eli Lilly, Sterling's '46 sales of medicines -- $86.7 million -- top the list for U.S. drug manufacturers (story on Sterling annual report, p. 1, WHITE SECTION); at least it's indicated Sterling's drug sales top all cos. which publish annual reports. American Home's total '46 sales were $132.3 million (up from $108.7), but '45 sales breakdown ('46 not available yet) gave drugs only 55% of AMHO's total business (ethicals 33%, packaged 22%). With AMHO also prominent in foods, it's doubtful whether the medicine portion shot up enough during '46 to top Sterling's drug sales. Other cos. primarily in proprietary or toiletry manufacturing field, but with widely diversified subsidiaries, are: Bristol-Myers, '45 sales $37.1 million -- '46 sales not available yet, but '46 net income figures indicate sales will top '45; Vick, reporting on a June 30 fiscal basis, '46 sales $37.1 (sales for last 6 months of '46 at $25.3); Lambert, '46 sales $30.2 million -- down fractionally from '45, but net income and earnings per common share up.

Lilly, which doesn't report financial data, may top Sterling's medicine sales. Trade analysts say Lilly sales top all pharmaceutical cos. -- this would put its '46 sales above Parke-Davis' reported $66.2 million. Industry guessers put Lilly's annual total between $75 and $100 million, -- if the latter, Lilly would top Sterling's $86.7 million. In analyzing sales figures for pharmaceutical cos., F-D-C REPORTS for March 22 noted that the only published figure on Lilly sales was $27.7 million, in 1945 House subcmte. testimony by FTC's Chief Statistician Roger Barnes. This figure was given as Lilly's '43 total, but a re-check shows that Mr. Barnes gave it as the '[redacted]-not '43-- total. Also March 22 analysis didn't mention Upjohn (it doesn't report either), but this co. also is among leading pharmaceutical firms, probably 4th or 5th. Lineup of pharmaceutical "big six" thus appears to be: Lilly, Parke-Davis ($66.2 million), Squibb ($59.8,including cosmetics and toiletries), Abbott ($54.2) or Upjohn, S & D($26.6) Mead Johnson ($22.9) may soon make it a pharmaceutical "big seven".

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Technically, Fishbein is still "limited" to editing AMA publications and handling scientific side of AMA's PR, but actually situation is Status quo ante. Re widespread daily press reports (particularly NY Times) that Fishbein's "wings had been clipped", F-D-C July 6, 1946 predicted: "It would take more than an exec. asst. to AMA Genl. Mgr. (Swart) to materially reduce Fishbein's influence." With characteristic unconcern, Fishbein left this week for trip to South America.

* * * * * DRUG WHOLESALERS ARE QUIETLY STUDYING how to shift increased pharmaceutical volume from co. branches to their own houses. Problems involved are too intricate for any sudden or dramatic moves, but increased operating costs for branch houses (primarily labor) give wholesalers a starting point. Other talking points -- prepaid deliveries and faster service than br[redacted]s.

Mutual advantages from Lilly's contract with 225 wholesalers (5 are rumored to handle more than $1 million Lilly volume annually) make it difficult for other pharmaceutical houses and wholesalers to make equally attractive arrangements. To change situation materially, other pharmaceutical houses must either increase discounts to wholesalers or decrease them to direct retail accounts; latter would cause a storm -- a good guinea pig, one Chicago drug store doing a $70,000 annual volume, buys direct from 11 houses and is very satisfied.

Wholesalers also have to prove they can do a good job on competitive pharmaceuticals and specialties. It's the difference between taking orders for a single line and adequately servicing a number of lines. Topsiders and salesmen must become more pharmaceutical minded; latter need more professional training. Current wholesaler thinking and research has been pointed to faster moving, large-order goods. One Los Angeles house was recently surprised when a check-up revealed it did a $1 million volume on small pharmaceutical orders.

* * * * * NEW, STRONGER LANGUAGE FOR SEIZURE AMENDMENT to F-D-C Act is being prepared by House Interstate Commerce subcmte. Members want to make sure F&DA's authority extend to the full sweep of the federal govt.'s constitutional powers under commerce clause. In addition to closing breach made by Phelps-Dodge decision, they are thinking about 5th Circuit's Sullivan decision (Petition for Certiorari has been filed with Supreme court). Bill or cmte. report may clarify Congressional intent to have law reach intrastate acts (over-counter sales) that affect effectiveness of interstate regulations (Rx legend).

But there may be opposition after the subcmte. gets through. For example, some canners are quietly but effectively lobbying against stretching interstate authority to cover Phelps-Dodge seizure. Also there's Rep. Landis (R. Ind.) so-called "tomato canners" bill (HR 3763). In addition to amending food adulteration and standardization provisions (tomato canners have trouble with F&DA's mold count), several general provisions would affect drug-cosmetic industries, including (1) Repeal mandatory factory inspection; (2) Give claimants full F&DA analytical data in advance of seizure trial.

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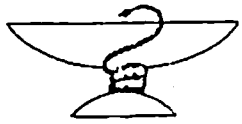
DE RE MEDICA

Editio Tertia



INDIANAPOLIS, INDIANA, U.S.A.

ELI LILLY AND COMPANY

1951

due to estrogen and progesterone during pregnancy must be distinguished from pathological causes of leukorrhea (see p. 197). Coitus during pregnancy probably increases the natural secretion. In the presence of vaginal infection, active treatment may be carried out until the seventh month of pregnancy. When leukorrhea is profuse in the absence of infection, cleansing douches may be employed up to the seventh month.

In order to prevent reflex pelvic congestion, the patient should dress warmly when out in cold weather. Full-length stockings should be worn, and these should preferably be heavy rather than sheer.

ABORTION

Abortion threatens at one time or another in at least 16 percent of all pregnancies, and spontaneous abortion occurs in about 10 percent. This means that without treatment six out of sixteen (or about 40 percent) of threatened abortions do not abort, whereas without treatment ten out of sixteen (or 60 percent) do abort. In about two-thirds of spontaneous abortions, the product of conception is defective or has died before the onset of abortion or for some other reason probably could not have been saved; but it is estimated that one-third of spontaneous abortions are theoretically salvageable at the time the patient is first seen by the physician. Thus, under treatment, there is potential salvage of not only the 40 percent of threatened abortions that would have continued to term without treatment, but also of the 20 percent (one-third of the 60 percent that aborted) considered salvageable by treatment.

The maintenance of pregnancy appears to depend primarily on a continued supply of estrogen and progesterone secreted by the placenta or by the corpus luteum of pregnancy under stimulation by chorionic gonadotrophin formed in the fertilized ovum or placenta. Death of the ovum, embryo, or fetus leads to cessation of estrogen and progesterone production. There may be a dangerous drop in hormone output during the twelfth to sixteenth week, when chorionic gonadotrophin production is diminishing and estrogen and progesterone production by the placenta is not yet fully under way. In spite of normal hormone production, the uterus may be stimulated to empty itself by extrinsic factors or by abnormal conditions of the endometrium or decidua. Maternal factors include low implantation of the placenta, uterine abnormalities (e.g., fixed retroversion, fibroid tumors), febrile and inflammatory disease, hypothyroidism, toxemia of pregnancy, and trauma.

An abortion is termed "missed" when the fetus is dead but abortion has not occurred within a few days. It is "incomplete" when fragments of the products of conception remain in the uterine cavity. It is "threatened" when vaginal bleeding or uterine cramps or both indicate that the membranes have begun to separate from the decidua or strong uterine contractions have begun, or both. It is "imminent" when these manifestations are so severe that the abortion can probably not be prevented. "Habitual abortion" is the term applied when the occurrence of two or more consecutive spontaneous abortions suggests that there is a high probability that succeeding pregnancies will end in the same way.

Abortion is sometimes undertaken therapeutically when continuation of pregnancy involves grave risk to the life or health of the mother. Curettage of the uterus in the first trimester, abdominal or anterior vaginal hysterotomy in the second trimester, and induction of labor or cesarean section in the third trimester constitute the only safe and accepted methods for therapeutic abortion. There is no known medication that will induce abortion except as a secondary effect of serious intoxication.

Treatment—When abortion threatens, the first principle is to keep the patient and her uterus quiet. She is put to bed, and sedatives (p. 390) or analgesics (p. 405) or both are administered as indicated. There should be no abdominal or vaginal manipulation, and laxatives and enemas are withheld.

Recent evidence indicates that the percentage of cases salvaged can be considerably increased by oral administration of diethylstilbestrol (p. 467). Dosage is not entirely settled, but an effective schedule seems to be 25 mg. as soon as the diagnosis is made, followed by 5 mg. every fifteen minutes or 25 mg. every hour until bleeding or cramps or both have ceased. After this, 5 mg. are given three times daily. It is difficult to determine when the drug can be safely discontinued. There is no harm in continuing it through the thirty-sixth week. If threatening symptoms recur, the original schedule is repeated.

Progesterone (p. 468) has been used in threatened abortion, but the amount required (at least 10 mg. daily) is large and it does not seem to be as effective as diethylstilbestrol.

If abortion actually occurs (as indicated by passage of membranes or fetus or both), diethylstilbestrol is discontinued and oxytocics (p. 476) are given, preferably ergonovine maleate, 0.2 to 0.4

mg. every six hours until bleeding ceases or for a maximum of two days. If incomplete abortion is not completed within two days (as shown by careful examination of expelled material) or if bleeding persists or is profuse, curettage should be performed. At its completion, ergonovine maleate may be administered intravenously. Infection, which contraindicates curettage, should be treated with systemic anti-infective agents (p. 286).

The treatment of habitual abortion should preferably start before conception with correction of all demonstrable endocrine and nutritional disturbances in both prospective mother and father. In particular, thyroid (p. 456) is advocated when there is any evidence of hypothyroidism (p. 180).

In the absence of hypothyroidism, probably the most effective agent is diethylstilbestrol. Its administration should be begun after pregnancy occurs but well before the expected threat of abortion. The dosage may be the same as that given during the corresponding week of pregnancy as prophylaxis against toxemia of pregnancy (see below).

Progesterone has been advocated (for dosage and administration, see p. 468), but it is apparently less effective than diethylstilbestrol. Administration of vitamin E (p. 497) has been proposed, but the results are hard to evaluate.

In the presence of retroversion, a pessary should be worn until the uterus has risen well out of the pelvis.

NAUSEA AND VOMITING OF PREGNANCY

One-half to two-thirds of women have some degree of nausea and vomiting during the first trimester of pregnancy. It usually begins about the sixth week and may last as long as two or three months. The cause has not been definitely established, but several lines of evidence point to an allergic mechanism. As in other forms of allergy, emotional and psychic factors may be extremely important.

In some patients the vomiting is severe enough to lead to serious dehydration (hyperemesis gravidarum). Possible causes outside of pregnancy should always be considered.

Many types of treatment have been advocated in the past. The most effective now seems to be an antihistaminic drug (p. 509). The dosage may have to be large (e.g., 50 to 100 mg. of 'Histadyl' three or four times daily), and sometimes better results are obtained if pyridoxine hydrochloride (p. 489) is added in doses of 50 to 100 mg. or more daily. In severe cases, initial doses should be intravenous. After relief has been obtained, the oral route may be used, and the dose and frequency of administration can often be reduced. In very mild cases the oral route may be effective from the beginning. In very resistant cases, concomitant administration of 50 to 100 mg. of thiamin chloride (p. 484) is often of value. However, intravenous administration of thiamin chloride is not recommended because of the possible development of sensitivity following repeated doses by this route.

If drug therapy is relatively ineffective, the physician should investigate the emotional factors. Particular attention should be directed toward the possibility that the pregnancy is not desired or that there has been undue mother attachment or difficulties in the sexual field.

Traditional measures which are sometimes helpful include frequent small feedings of solid food, avoidance of fluids within an hour before or after meals, taking of dry crackers or toast before arising (in cases of morning nausea), and mild sedation.

If the patient is able to retain little or no food or liquid, she should be hospitalized promptly. Extragenital causes and genital causes outside the pregnancy (such as retroflexed uterus or ovarian cyst) should be ruled out. Special nursing care is provided, and all visitors, including the husband, are barred. Nothing but a small quantity of cracked ice is allowed by mouth, and the patient is treated as for dehydration (p. 56). Adequate psychotherapy should be undertaken.

If there is considerable improvement after two days, solid foods may be given while parenteral fluids are continued. A general diet and fluids by mouth are gradually resumed as tolerated. If improvement does not occur, fluids, vitamins, and carbohydrate are given by duodenal tube. If, in spite of treatment, the condition becomes worse, consultation should be sought with a view to emptying the uterus. Indications for therapeutic abortion in hyperemesis gravidarum include persistent tachycardia, jaundice, fever, hypotension, psychosis, or loss of twenty pounds' weight. Local or regional anesthesia should be employed.

TOXEMIA OF PREGNANCY

Toxemia of pregnancy (eclampsia and pre-eclampsia) is the third largest cause of maternal mortality. It is a specific condition peculiar to pregnancy. Its onset is limited to the latter half of pregnancy, and typically it recedes completely prior to or shortly after delivery. Its manifestations include one or more of the following: hypertension, proteinuria, generalized edema. In full-blown cases there may

TABLE 21—*Dosage Schedule for Oral Administration of Diethylstilbestrol in Prevention of Accidents of Pregnancy*

Week of Pregnancy, Dating from First Day of Last Menstrual Period	Daily Dose
7th and 8th	5 mg.
9th and 10th	10 mg.
11th and 12th	15 mg.
13th and 14th	20 mg.
15th	25 mg.
16th	30 mg.
17th	35 mg.
18th	40 mg.
19th	45 mg.
20th	50 mg.
21st	55 mg.
22d	60 mg.
23d	65 mg.
24th	70 mg.
25th	75 mg.
26th	80 mg.
27th	85 mg.
28th	90 mg.
29th	95 mg.
30th	100 mg.
31st	105 mg.
32d	110 mg.
33d	115 mg.
34th	120 mg.
35th	125 mg.
36th	Drug discontinued

presenting part and is well engaged and the cervix is already partly effaced and dilated.

Medical induction is less frequently successful, but it avoids vaginal entry and artificial breach of the membranes. The myometrium may be made more responsive by administering diethylstilbestrol (p. 467) on the day before induction (10 or 15 mg. once an hour by mouth for ten doses). On the day of induction the following schedule may be carried out:

6 a.m.—castor oil, 2 oz.

8 a.m.—hot soapsuds enema

10 a.m.—posterior pituitary extract, 2 U.S.P. Units hypodermically or intranasally (p. 474)

If labor does not set in, the posterior pituitary is repeated at half-hour intervals for a total of four doses. If no labor results, the patient is given another hot soapsuds enema at seven in the evening, and posterior pituitary is again given for no more than four doses at half-hour intervals.

Quinine was formerly used, but its advisability has been questioned because it apparently may cause deafness in some of the babies. Posterior pituitary should not be given to a patient with toxemia of pregnancy or severe hypertension.

Pain Relief—It has been demonstrated that judicious pain relief during labor and delivery results not only in greater comfort for the mother but also in lower mortality rates for both mother and baby. There is, however, still considerable controversy among obstetricians as to the relative merits of the different means of providing pain relief.

The need for pain relief varies greatly among women. In general, there is discomfort beginning with the actual onset of labor. The most that is needed during this period is mild sedation. Women who are not apprehensive need nothing. Sooner or later the discomfort progresses to the point where relief is justified. Here one can employ systemic narcotic or hypnotic drugs which produce analgesia or amnesia or both, or one can administer regional nerve block. Toward the end of the second stage of labor a much greater degree of relief is usually necessary, and one may add to previous measures inhalation or intravenous anesthesia or regional or spinal nerve block.

Agents and methods commonly employed are listed below. They are discussed and their use outlined in the cross references given.

- General inhalation anesthetics
  - Volatile agents
    - Ether (p. 411)
    - Chloroform (p. 412)
  - Gaseous agents
    - Nitrous oxide (p. 412)
    - Ethylene (p. 412)
    - Cyclopropane (p. 413)
- Systemic analgesic agents
  - Narcotic and amnesic agents
    - Morphine and opium (p. 399)
    - Synthetic morphine-like drugs (p. 404)
    - Scopolamine (p. 421)
  - Hypnotic agents
    - Barbiturates (p. 394)
- Drugs given intravenously
  - Barbiturates (Pentothal Sodium) (p. 394)
- Drugs given rectally
  - Ether (p. 411)
  - Paraldehyde (p. 398)
  - Barbiturates (p. 394)
- Regional anesthesia (p. 457 *et seq.*)
  - Infiltration of perineum
  - Pudendal block
  - Continuous caudal anesthesia
  - Terminal caudal block
  - Continuous lumbar epidural anesthesia
  - Continuous spinal anesthesia
  - Terminal spinal anesthesia, including saddle block

THE MODERN

Apothecary

A COMPENDIUM IN FOUR PARTS

A COMPILATION OF AUTHORITATIVE MATERIAL CALCULATED TO PROVE HELPFUL TO PHARMACISTS WHO ARE PRIMARILY INTERESTED IN THE PROGRESS AND DEVELOPMENT OF THEIR PRESCRIPTION DEPARTMENTS

Published by

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THE
MODERN APOTHECARY

EDITED AND COMPILED BY

H. S. NOEL.

DIRECTOR TRADE RELATIONS

ELI LILLY AND COMPANY

Study Prescribing Habits

A study of the prescribing habits and needs of the physicians in any given locality is helpful even if it is not altogether a specific against too much stock or too great a variety of stock. It is worthy of note that the National Drug Store Survey showed that from 44 percent to 89 percent of a pharmacy's total prescription business could be accounted for by its ten leading physicians. That does not mean that a drug store should not endeavor in every way to cultivate the patronage of additional physicians. Far from it.

An Aid in Balancing Stocks

As a guide for pharmacists confronted with the question of balanced stocks or an opening stock order, the leading ingredients that are found necessary in a drug store can be classified as follows: (1) chemicals; (2) galenicals and pharmaceuticals in general; (3) botanicals and oils; and (4) proprietaries and manufacturers' specialties.

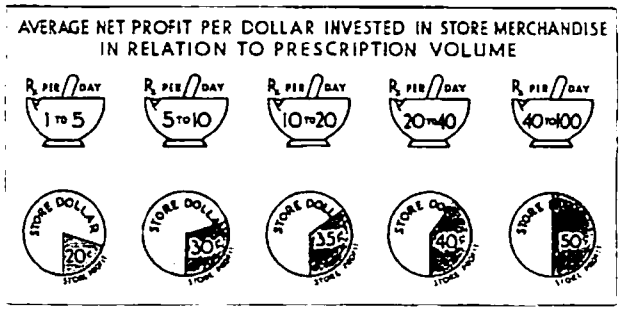
The following table is based on the studies of Professor E. N. Gathercoal, covering over 120,000 prescriptions in four widely separated states, combined with the figures provided by the National Drug Store Survey.

According to the Lilly Digest, as the number of prescriptions filled in a drug store increases, the likelihood of unsatisfactory gross margins decreases for the entire store. The following table reflects this tendency.

Percentages of Stores with Average Gross Margins Under 30 Percent of Sales

1 to 1,825 prescriptions	51%
1,826 to 3,650 prescriptions	21%
3,651 to 7,300 prescriptions	25%
7,301 to 14,600 prescriptions	17%
14,601 to 36,500 prescriptions	25%

It is of further interest to note the effect of prescription volume in increasing the average net profit per dollar invested in all store merchandise.



From the *Lilly Digest*

As prescription volume grows, certain basic stocks naturally may remain about the same but increased investment becomes necessary and more items must be carried. This is obvious. Less obvious, to many pharmacists, however, is the fact that the added

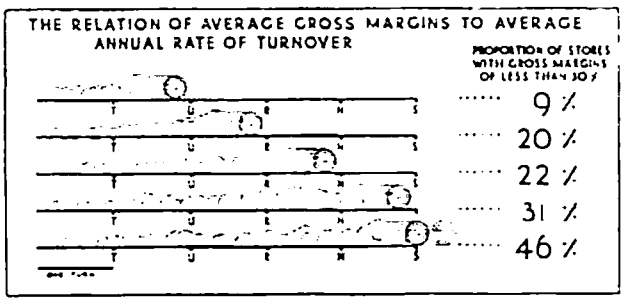
Summary of Ingredients Which Occurred Five Times or More Each

Type of Ingredient	Number of Ingredients	Percent of Total	Total Value of Opening Order	Average Cost per Item	Number of Times These Ingredients Were Prescribed: Total	Percent of Total	Average per Ingredient
Chemicals	164	24.0	$ 93.51	$0.57	22,087	51.3	135
Galenicals	234	34.2	206.15	0.88	11,357	26.4	49
Specialties	253	37.0	288.98	1.14	8,625	20.0	34
Botanicals, Oils, etc.	33	4.8	17.13	0.52	983	2.3	30
Total	684	100.0	$605.77	$0.89	43,052	100.0	63

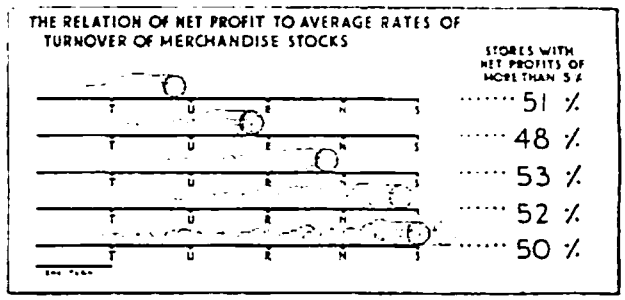
A detailed list of the ingredients, each of which appeared five or more times in 120,000 prescriptions, will be found in *The Professional Pharmacy*, published by the American Pharmaceutical Association, Washington, D. C. While the list is not new, nevertheless it will serve as an excellent guide to the selection of items that should be available in the stocks of a prescription department.

which the average investment in stock has been turned into cash, both figures representing cost prices instead of sales prices.

Turnover is determined by dividing sales at their cost price for a given period by the average inventory of store merchandise at cost for the same period. Many druggists justify their large stocks on the ground that the lower purchase price provides higher margins; therefore, such buying practices should provide greater net profit. This is a reasonable conclusion. In fact, field studies prove that gross margins are higher in stores with large stocks and low turnover than they are in stores carrying smaller merchandise stocks and having a fast turnover. Studies of the operations of 611 drug stores reported in the Lilly Digest show that 9 percent of the stores identified as heavily stocked establishments by the slowness of the turnover had gross margins of less than 30 percent. On the other hand, 46 percent of the stores identified as not heavily stocked because of a turnover of five times a year or more had margins of less than 30 percent.



Gross margin is one factor, net profit is another. An attempt was made, therefore, to determine how successful these same 611 stores were in converting gross margins into net profits according to the frequency of turnover. It was found that 51 percent of the stores turning stocks from once to twice yearly made net profits of more than 5 percent on sales. These are the stores that were identified as quantity buying stores by the slow movement of stocks. It was found that 50 percent of the stores that turned stocks five or more times a year made more than 5 percent net profits on sales. This was interpreted as meaning that there was virtually no difference in the likelihood of a drug store obtaining a net profit of 5 percent or more whether the store bought in quantities with resultant slow turnover or purchased stocks with the idea of securing a rapid turnover.



The real measure of success of a drug store is the amount of return obtained from each dollar invested. It is the criterion of success in the purchase of bonds, in the real estate business, or in the operation of a drug store. The paramount consideration is always the same. What does the investment yield?

Some pharmacists invest for gross margins in the hope that these margins will produce correspondingly large net profits. Some pharmacists try to increase the net profit by seeking a rapid turnover of stock. It is therefore particularly interesting to study the operations of these 611 drug stores from the angle of the average net profit these stores obtained, according to the turnover, per dollar invested. This is the same group of stores, studies of which revealed that the

October 22, 2003

* Corrections/additions underlined

CORRECTED STATEMENT OF PHILIP J. CAFFERTY*

I reside at 16 Triphammer Road, Hingham, MA 02043. I am 64 years of age and am a pharmacist and a former pharmaceutical representative of Eli Lilly and Co. I am familiar with the field of retail pharmacy inventory and stocking practices over the last 49 years in the Boston and Rhode Island areas, and the sales and marketing practices of Eli Lilly and Company for the last 49 years.

Career

1. I began my career in retail pharmacy in 1954 as a clerk and stock boy in a retail pharmacy in New England. Three years later, I began pharmacy school, but continued working in a retail pharmacy. From 1954, I have continuously been in the retail pharmacy industry as a clerk, pharmacist, detailman, or pharmaceutical district manager.

Licensing

2. I hold a degree in pharmacy from the University of Rhode Island and have been a licensed pharmacist since 1961, registered in the states of Massachusetts, Rhode Island and New York. I have been a member of the Massachusetts and Rhode Island Pharmacy Associations.

Scope

3. My employment in the field of pharmacy has given me the opportunity to be present at, observe, or converse with personnel in approximately 200 pharmacies in Massachusetts and Rhode Island over the last 49 years. In my experience over the last half century in dozens of drugstores, as a pharmacist, a pharmaceutical representative and detailman, both for Lilly and Miles Laboratory, I had the opportunity to review prescription forms, become familiar with drugs, drug popularity, as well as, physician prescribing habits. I have filled or reviewed drug prescriptions in the hundreds of thousands over the last 49 years. I am familiar with the practice of retail drugstores in the Boston and suburban retail pharmacies.

Lilly Employment

4. For 19 years commencing in 1965, I was employed by Eli Lilly and Company, Indianapolis, Indiana, as a professional representative or detailman and district manager. My duties included:

a. Calling on retail pharmacies to introduce new Lilly products, restocking shelves of the pharmacies with new inventory, maintaining inventory with proper shelf-life order, replacing outdated merchandise, credit for return. In this effort, I had responsibility for the stocking of Lilly products in approximately 200 pharmacies in Rhode Island and Massachusetts. In this position, I would have the

opportunity to cull through store prescriptions to observe physician prescribing habits.

b. Observing and originating reports regarding prescribing habits, frequency of prescription, popularity of prescription brands, drug indications, warnings, product presentation; and

c. Investigating physician's prescribing habits for both Lilly and competitors. Detailing physicians and pharmacists, which included observing shelf products for Lilly as well as for its competitors and speaking to doctors regarding their prescribing habits. Obstetricians and Gynecologists were some of the doctors I detailed.

Familiarity with the 1950s

5. I have actually filled over 14,000 prescriptions since 1957. Even though at first I was a pharmacy student under the supervision of a pharmacist, I had the opportunity to read prescriptions from physicians, fill, label, and dispense the medication in over 20 cities for over a half century. In addition, I commonly ordered pharmaceuticals from wholesalers and manufacturers. I also was familiar with pricing policy and coding. I averaged between 30 and 32 hours per week until 1961 when I graduated, became licensed and became engaged in full-time pharmacy practices. From then on, I was a full-time pharmacist.

Familiarity with DES

6. I am familiar with Diethylstilbestrol, also known as DES and Stilbestrol. I filled on the average of three or four prescriptions a week for DES starting in the late 1950s, but I have seen it on shelves in pharmacies since 1954. I knew it was indicated for prevention of miscarriage, among other uses, and I knew it came in different strengths from .1 mg to 25 mg. and in white uncoated tables as well as red-coated pills. Diethylstilbestrol was the only popular oral hormone medication given in the 1950s and 1960s to pregnant women. It was the drug of choice and the standard treatment for pregnant women and the only popular oral medication regularly used for this purpose. I am familiar with the Lilly publication "De Re Medica" that was sent to the physicians of America, which advocates DES as the best medication for avoiding miscarriage.

Review of Literature

7. I have reviewed the commercial DES literature including PDR, Redbook, Bluebook, and U.S. Pharmacopoeia from the 1950s and 1960s. I have also reviewed Lilly publications in general from the 1950s and 1960s, such as field reference manuals, product labeling, inserts, product brochures, Tile and Till, The Lilly Digest and other Lilly publications regarding competitive pharmaceutical manufacturers. I was familiar with this material in the 1950s, 1960s and 1970s. From these readings as well as my observations of the practice of pharmacy, I observed what changes if any occurred in the

marketing, ordering, stocking and dispensing of retail pharmaceuticals over the last half century. The practices have remained relatively stable during the last half century.

Lilly's Publications

8. I am familiar with Lilly's promotional publications in the 1950s, 1960s and 1970s especially De Re Medica, The Physician's Brochure, The Physician's Bulletin and other labeling. I recall detailing physicians in that period and observing these publications. I have seen them in drugstores, hospital pharmacies and doctor's offices.

Survey of Pharmacists

9. I have reviewed over 105 sworn statements of other pharmacists regarding the prevalence and availability of the Eli Lilly DES products in their stores in the 1950s and 1960s. I have personally spoken with 17 pharmacists in the New England area who were practicing in the 1950s and 1960s as to their recollection of the DES market. Results of this research point to Lilly as the unique and unrivaled supplier.

Lilly Products and Inventory

10. I recall the wholesaler strategy from the 1950s and 1960s by Eli Lilly and Company as well as their agreements with wholesalers throughout the country. Eli Lilly was the leading pharmaceutical manufacturer in America at that time with top market popularity because of its reputation, quality, control, efficiency of inventory and distribution through wholesalers. In the 1950s and 1960s Lilly was the only major pharmaceutical manufacturer from whom you could only order through a wholesaler and not directly from the company. Lilly was the only major drug house that employed licensed pharmacists as detailmen – this allowed them to have greater access to pharmacists and pharmacy stocking practices than any other company. Only the Lilly detailmen actually went behind the counter of a drugstore, pulled off outdated products and replenished the shelves. Lilly's practices enabled the retail pharmacists to save money. For example, DES was sold in eight forms: .1 mg, .5 mg, 5 mg and 25 mg both in coated and uncoated. This would require a pharmacist to invest in a minimum of eight bottles of 100 tablets. The pharmacist could receive a bottle at a time only from the Lilly wholesaler quickly, but for most of the other companies, ordering had to be done directly from the manufacturer, in larger orders, often taking a longer time requiring a greater investment in inventory at additional cost. Only Lilly, with its national network of Lilly wholesalers could allow a pharmacist to keep a single bottle of DES in one strength and color and get almost instant replenishment from the local wholesaler.

Generics

11. Regarding generic manufacturers and generic substitution as it is known today, this is a phenomenon of recent years only. In the mid and late 1950s, generic companies and generic drugs were virtually unknown and unused. It was not until the late 1960s the generics began their popularity.

October 22, 2003
* Corrections/additions underlined.

The Red and Blue Books do not Reflect the Market

12. I have reviewed the Red and Blue Books as well as the PDR for 1954 and 1958 ad it applies to DES. Although the Red and Blue books may have listed many brands of DES available in the world, it is not an accurate presentation of the DES market in Massachusetts and Rhode Island during the 1950s and 1960s – the years of DES popularity. In all the pharmacies I have visited in Massachusetts and Rhode Island and of the hundreds of pharmacists I have talked to, I have never seen or heard of a DES product not manufactured by Eli Lilly. Perhaps some of the brands listed in the Red or Blue Books were dispensed in the South or on the West Coast, but not in Massachusetts or Rhode Island in any numbers. I have seen only Lilly's DES products in the drugstore of the Boston suburbs. If a doctor had specified a Squibb or Upjohn product, I am sure that the pharmacist would have had to fill the prescription that way, but if it were prescribed as merely DES, Stilbestrol or Diethylstilbestrol, it would have been filled with a Lilly product.

Continuity

13. I spent one year in the home offices of Eli Lilly in the creation of marketing plans and was a sales manager, having 12 detailmen under me, thus enabling me to observe, in addition to my other experiences, Lilly's pharmaceutical marketing and their manipulation of markets throughout America in distribution, sales practices, sales techniques and sales strategies. These strategies, customs and practices did not significantly change between the mid-1950s and late 1970s. The DES market in the mid-1950s remained the same through the 1960s.

Wholesaler Agreements

14. I have reviewed the Eli Lilly distributing and selling service agreement and Eli Lilly Warehousing and Distribution Service agreements. I have personal knowledge of their existence and workings over the last 45 years. Lilly entered into agreements with the following wholesalers in the New England area, with whom I am familiar: McKesson Robbins Company, the Gilman Brothers Company and the James W. Daly Cardinal Company. They were Lilly wholesalers and they controlled the Boston and Rhode Island pharmaceutical wholesaler distribution field. Under the agreement, these pharmaceutical wholesalers were obligated to provide a Lilly product "on all unspecified orders." The effect of this agreement was that if a local retail pharmacy ordered "DES," "Diethylstilbestrol" or "Stilbestrol" from these wholesalers, they would receive a Lilly product. The wholesaler was required to send a Lilly product or lose the Lilly account, which in those days was the biggest. I recall there were other brand name DES products. Squibb made a DES called Stilbetin and Upjohn made a DES called Perles, but these were trade names and had to be ordered that way by the physicians. Plain "DES" was always Lilly.

October 22, 2003
* Corrections/additions underlined.

Pill Description

15. The 25 mg. (pregnancy size) DES manufactured by Eli Lilly was a round, white, cross-scored tablet without any other markings. It is pictured in the attached photograph. I am familiar with that drug having dispensed it on hundreds of occasions. No other manufacturers have such a DES product.

Conclusion

16. Based upon my observations of drugstores and familiarity with the pharmaceutical field, Lilly had the lion's share, if not all of the DES market. I observed no other brand of DES in stores in Boston and Rhode Island. Based on my experience and observations, it is inconceivable that I would not have seen or heard of a non-Lilly brand, had it been there.

I declare under penalty of perjury that the foregoing statement is true and correct and is based upon my personal knowledge of the facts set forth.

Date: 11/17/03

Philip J. Cafferty, R.Ph.

Witness: